UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,159	06/24/2003	Nebojsa Janjic	NEX66/D2	3567

25871 7590 08/28/2009
SWANSON & BRATSCHUN, L.L.C.
8210 SOUTHPARK TERRACE
LITTLETON, CO 80120

EXAMINER
VIVLEMORE, TRACY ANN

ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
08/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efspatents@sbiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/606,159	JANJIC ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *1-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 1-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 16, 2006.

Double Patenting

Claims 7-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 15, 26, 27 and 34 of U.S. Patent No. 6,582,918 in view of Gold et al. (of record) and Zimmerman et al. (US 5,425,940). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims are directed to methods that comprise the same steps as the instant claims.

Instant claims 7 and 9 are directed to methods of improving the pharmacokinetic properties of a PDGF nucleic acid ligand comprising the steps of covalently linking a PDGF nucleic acid ligand of SEQ ID NO: 146 with a non-immunogenic, high molecular weight compound or lipophilic compound to form a complex and administering said complex to a patient. Claim 9 recites the inclusion of 5' 40K PEG, which is a structure shown in instant figure 9A.

Claims 15 and 27 of the '918 patent are directed to methods of treating fibrosis or inhibiting restenosis and claim the same steps as the instant claims: forming a complex of a PDGF nucleic acid ligand with a non-immunogenic, high molecular weight compound or lipophilic compound to form a complex and administering said complex to a patient. Claims 26 and 34 recite that the methods are performed with a complex that comprises SEQ ID NO: 146 and has the PEG structure of instant claim 9. Because claims 15 and 27 recite method steps identical to those of the instant claims and claims 26 and 34 recite the methods are performed with a complex having the structure recited in claim 9, these claims anticipate claims 7 and 9. Further, because the method steps are identical, it would be expected in the absence of evidence to the contrary that performing the method of either claim 15 or claim 27 will have the effect of improving the pharmacokinetic properties of the PDGF nucleic acid ligand.

Instant claim 8 is directed to a method of targeting a therapeutic or diagnostic agent to a location expressing PDGF in a patient comprising the steps of covalently linking a therapeutic or diagnostic agents to a complex comprising the PDGF nucleic acid ligand of SEQ ID NO: 146 and a non-immunogenic, high molecular weight compound or lipophilic compound to form a complex and administering the complex to a patient. Claim 10 recites the use of the 5' 40K PEG described above.

Claim 12 of the '918 patent is directed to a method of inhibiting the growth of tumors expressing PDGF by forming a complex of a PDGF nucleic acid ligand with a non-immunogenic, high molecular weight compound or lipophilic compound to form a complex and administering said complex to a patient. When performing this method,

one of ordinary skill in the art would look to the working examples of the '918 patent for guidance regarding suitable nucleic acid ligands targeting PDGF and would find that the patent teaches that SEQ ID NO: 146 conjugated with 5' 40K PEG is efficacious in inhibiting restenosis and treating glomerulonephritis.

While claim 12 of the '918 patent does not teach combining the nucleic acid ligand complex with a therapeutic agent, one of ordinary skill in the art would it obvious to do so because Gold et al. (of record) teach that nucleic acid ligands can be used as a drug delivery vehicle and those in the art recognize (see Zimmerman et al., column 3) that cancer therapies routinely involve combinations of therapeutic agents. Based on these teachings, one of ordinary skill in the art would have reason to link the agent to the nucleic acid ligand complex of claim 12 in order to use a nucleic acid ligand in the manner suggested by Gold et al. Thus claims 8 and 10 are an obvious variation of claim 12 of the '918 patent in view of the teachings of Gold et al. and Zimmerman et al.

Response to Arguments

Applicants argue the cited patent claims do not teach or suggest the instant claims 7-10 because they do not mention enhancing pharmacokinetic properties of a PDGF nucleic acid ligand or targeting of a therapeutic or diagnostic agent to a specific biological target that is expressing PDGF in a patient. With regard to claim 7, applicant asserts that the examiner relies upon a portion of the '918 patent for the concept that the association of a non-immunogenic, high molecular weight compound or lipophilic

compound will result in improved pharmacokinetic properties and argue that this reliance is improper under the standards of *In re Vogel*.

Applicants appear to misunderstand the basis for the rejection, which does not rely on the '918 specification. The rejection stated that "...because the method steps are identical, it would be expected that performing the method of either claim 15 or claim 27 will have the effect of improving the pharmacokinetic properties of the PDGF nucleic acid ligand." The reference to the '918 specification was made only to note that it supports the conclusion already made: that methods which share identical steps will have the same effects. In order to avoid further confusion, the rejection has been revised to make clear that the rejection stands on its own and does not require reliance on the '918 specification.

With regard to the rejection of claims 8 and 10, applicants argue that neither Gold et al. nor Zimmerman et al. mention or suggest the conjugation of an agent to a complex of a nucleic acid ligand and a high molecular weight compound or lipophilic compound and assert there is insufficient reason to combine the claims of the '918 patent with these references.

This argument is unpersuasive because while it is correct that the teachings of Gold et al. are directed to nucleic acid ligands rather than complexes of nucleic acid ligands and another molecule, this reference teaches that one use for nucleic acid ligands is as drug delivery vehicles. One of ordinary skill would readily recognize that this use would include embodiments wherein the nucleic acid ligand and agent are covalently linked.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is (571)272-2914. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz, can be reached on 571-272-0763. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

(EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Primary Examiner
Art Unit 1635

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635